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COMMITTEE ON THE BUDGET

July 21, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

The Honorable Stephen Hahn
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Secretary Azar and Commissioner Hahn,

As you are both aware, the Food and Drug Administration (FDA) rescinded its emergency use authorization for Hydroxychloroquine to treat COVID-19 on June 15, 2020. The FDA followed up on July 1, 2020 with a comprehensive summary of the safety issues associated with hydroxychloroquine to treat hospitalized patients with COVID-19[1]. This report confirmed many of the fears that have been reported about the use of hydroxychloroquine for COVID-19 patients: use of this drug results in heart problems, blood and lymph disorders, kidney injuries, and liver problems and failure.

On April 23, 2020, I sent a letter to VA Secretary Wilkie with serious concerns about prescribing this drug to our nations veterans who were diagnosed with COVID-19. Fifty days later, the Secretary Wilkie responded to my questions and included that the Department of Veterans Affairs had spent $2 million taxpayer dollars to acquire additional hydroxychloroquine even with mounting evidence and research that the use of this drug for COVID-19 patients was unproven and potentially deadly.

In the recently released data from the FDA, 109 cases of individuals treated with hydroxychloroquine experienced serious cardiac adverse events, with 25 unfortunately having a fatal outcome. Additional patients treated with hydroxychloroquine experienced serious non-cardiac adverse events including liver failure, kidney/renal failure. Some cases were even fatal with patients dying from methemoglobinemia (MetHb) as a result of taking hydroxychloroquine.[2]

It is clear – this drug is creating more harm to patients than good. I have been extremely troubled to see recent administration officials renew calls for a new emergency use authorization for

[1] https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or
[2] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/OSE%20Review_Hydroxychloroquine-Cholorquine%20-%2019May2020_Redacted.pdf

hydroxychloroquine. This flies in the face of scientific data and research from our own U.S. agencies charged with regulating the drug.

To that end, I would like to know the following details questions:

- How many doses of hydroxychloroquine were purchased by the Strategic National Stockpile for off-label use related to COVID-19 in health care settings?
- How many doses of hydroxychloroquine were donated to the Strategic National Stockpile for off-label use related to COVID-19 in health care settings?
- How many doses of hydroxychloroquine remain in the Strategic National Stockpile?
- How much have HHS-administered health programs, including Medicare, Medicaid, and the Children's Health Insurance Program paid in reimbursement for the off-label use of hydroxychloroquine related to COVID-19?
- What plans are HHS making for the distribution for remaining doses for on-label uses of hydroxychloroquine?
- Does the FDA have any plans to consider issuing a new emergency use authorization for this drug and if so, based on what data and research?
- In light of continued guidance and recommendations from the FDA, have healthcare providers sought to return or sell large purchased amounts of hydroxychloroquine?
- Hydroxychloroquine is an effective treatment for individuals suffering from diseases such as lupus, malaria, and rheumatoid arthritis. There is tremendous concern in the medical community that the off-label use of hydroxychloroquine will lead to shortages for individuals who are prescribed the drug. How has HHS helped ensure patients prescribed hydroxychloroquine conditions such as malaria, lupus, and rheumatoid arthritis will not face barriers to having their prescriptions filled for this life-saving and life-sustaining medication?

Given the evolving nature of the U.S. fight against COVID-19 and the urgent need to provide Americans with the best healthcare and information available, I ask you to respond to these questions no later than July 31, 2020.

Sincerely,

Rosa L. DeLauro
Member of Congress